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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,237

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Gregory S. Kelley

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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER

GOFF II, JOHN L

ART UNIT

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12/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,237	Applicant(s) KELLEY, GREGORY S.	
	Examiner John L. Goff	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-27 is/are pending in the application.
- 4a) Of the above claim(s) 21, 24 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20, 22, 23, 25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the amendment filed on 7/17/09.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 17, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil et al. (U.S. Patent 5,320,634) in view of Larmour (U.S. Patent 2,237,152) or Most (U.S. Patent 2,127,043).

Vigil discloses a method for manufacturing a cutting balloon catheter comprising providing a strip of polymeric material/joining member (32 of Figure 2(A)), providing a metallic cutting member/blade the cutting member having a cutting surface (31 of Figure 2(B)), a top surface (30, 33a, and 33b of Figure 2(B))), and a base having a plurality of openings (35a, 35b, and 35c) which define an interlocking surface, embedding and securing the cutting member into the strip so that the interlocking surface is submerged and interlocked with the strip and so that a portion of the top surface is submerged within the strip, and attaching the strip with embedded cutting member to an angioplasty balloon (12 of Figure 1) (Column 4, lines 1-46). Vigil does not specifically teach how the cutting member, a metal blade, is embedded in the strip, a polyurethane strip. It is extremely well known in the art to inexpensively embed a metal member within a strip of polymeric material by heating the strip to soften, melt and liquefy at least a portion of the strip, disposing the metal member adjacent the strip, submerging at least a portion

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of the metal member in the liquefied portion, and cooling to solidify the strip and interlock the metal member and strip as shown by Larmour (Figures 1 and 2 and Page 1, Column 1, lines 32-35 and 44-49 and Page 2, Column 1, lines 3-5 and 21-25) or Most (Page 1, Column 2, lines 26-32 and 49-52 and Page 2, Column 2, lines 24-31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to embed the cutting member within the strip of polymeric material as taught by Vigil using a well known inexpensive method including heating the strip to melt and liquefy at least a portion of the strip as shown by Larmour or Most.

As to the limitation of “so that a portion of the top surface is submerged within the joining member”, Figure 2(A) of Vigil does not depict the top surface (30, 33a, and 33b of Figure 2(b)) of the cutting member/blade such that the top surface is considered submerged within the joining member, and more specifically Vigil depicts dashed line 39 showing the submerged structure including the surfaces (30, 33a, and 33b). Furthermore in the event it were shown that Virgil does not expressly disclose the limitation the following rejection would apply, it would have been obvious to one of ordinary skill in the art at the time the invention was made that embedding the cutting member/blade as taught by Vigil as modified by Larmour or Most would have included embedding the top surfaces (30, 33a, and 33b) to some extent to firmly interlock the strip with the cutting member/blade as Figure 2(A) of Vigil does not depict at least a portion of the top surfaces (30, 33a, and 33b) and the extent embedding is not critical in Vigil other than the top surface used for cutting (31 of Figure 2(B)) is not embedded as shown by Figure 2A and dashed line 39.

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4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil and Larmour or Most as applied to claims 17, 18, and 20 above, and further in view of Lim et al. (U.S. Patent 7,147,619).

Vigil and Larmour or Most as applied above teach all of the limitations in claim 19 except for a specific teaching of heating to melt the strip of polyurethane using a laser. Vigil as modified by Larmour or Most is generally directed to heating the strip of polyurethane to melt the strip wherein the specific means for application of heat is not critical or limited. It was known in the art that it was suitable to heat polyurethane portions of a catheter to its melting temperature using a laser as shown by Lim (Column 9, lines 1-8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to heat the strip of polyurethane taught by Vigil as modified by Larmour or Most to melt the strip using any known suitable means such as laser as shown by Lim only the expected results being achieved.

5. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil and Larmour or Most as applied to claims 17, 18, and 20 above, and further in view of Forman et al. (U.S. Patent 5,514,092).

Vigil and Larmour or Most as applied above teach all of the limitations in claims 22 and 23 except for a specific teaching of attaching the strip to the balloon by heating. Vigil suggests as exemplary attaching by adhesive, but Vigil is not limited to any particular attaching means. It was known in the art that it was suitable to attach the balloon of the catheter to other members using any of heat with laser, adhesive, etc. as shown by Forman (Column 9, lines 5-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the strip to the balloon as taught by Vigil as modified by Larmour or Most using any of laser

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welding, adhesives, etc. as was known as suitable as shown by Forman wherein laser welding has the obvious advantage of not requiring an adhesive.

6. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil and Larmour or Most as applied to claims 17, 18, and 20 above, and further in view of Radisch (U.S. Patent 2003/0040770).

Vigil and Larmour or Most as applied above teach all of the limitations in claim 25 except for a specific teaching of disposing a second cutting blade adjacent and within the strip. It was known in the same art to include more than one cutting blade adjacent and within the strip to form an effective cutting edge that conforms to the surface being cut as shown by Radisch (Paragraph 0028). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include adjacent the strip taught by Vigil as modified by Larmour or Most at least a second cutting blade to form an effective cutting edge that conforms to the surface being cut as shown by Radisch.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil and Larmour or Most as applied to claims 17, 18, and 20 above, and further in view of Obara et al. (U.S. Patent 4,581,513) or Gray et al. (U.S. Patent 5,895,406).

Vigil and Larmour or Most as applied above teach all of the limitations in claim 27 except for a specific teaching of forming the plurality of openings in the metallic cutting blade using a wire electric discharge milling technique, it being noted Vigil is silent as to how the openings are formed. It was known in the art to cut metallic members including those small in size with precision using a wire electric discharge milling technique as shown by Obara (Column 1, lines 5-29) wherein Gray (Column 4, lines 62-65) evidences specifically using electric

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discharge milling in cutting a metallic member used in a catheter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the plurality of openings in the metallic blade taught by Vigil as modified by Larmour or Most using a known suitable and precise technique such as wire electric discharge milling as shown by Obara or Gray.

Response to Arguments

8. Applicant's arguments filed 7/17/09 have been fully considered but they are not persuasive.

Applicant argues, "As indicated in the Office Action, nothing in Vigil et al. appears to teach or suggest positioning the cutting blade adjacent the joining member so that the interlocking surface is submerged within and interlocked with the joining member and so that a portion of the top surface is submerged within the joining member. Likewise, nothing in Larmour or Most teaches or suggests this feature. Therefore, nothing in the teachings of the cited art render the claimed invention obvious."

Figure 2(A) of Vigil does not depict the top surface (30, 33a, and 33b of Figure 2(B)) of the cutting member/blade such that the top surface is considered submerged within the joining member. Moreover, Vigil expressly depicts dashed line 39 showing the submerged structure including the top surfaces (30, 33a, and 33b). Vigil teaches at column 4, lines 31-34, "As indicated in FIG. 2B, structure 30 will be embedded into polyurethane substrate 32 (See FIG. 2A) to cover the structure 30 from hash-marked line 39."

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Applicant further argues, “Indeed, if the top surface (e.g., cutting edge 31) was submerged within the substrate 32, it would certainly render the atherotome 28 unsatisfactory for its intended purpose.”.

Vigil teaches a cutting blade having a cutting surface (31 of Figure 2(B)), a top surface (30, 33a, and 33b of Figure 2(B)), and a base (35a, 35b, and 35c of Figure (2B)) substantially identical to that depicted in applicants Figure 3 wherein Vigil does not submerge the cutting surface the same as applicants otherwise neither cutting blade would work.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **John L. Goff** whose telephone number is **(571)272-1216**. The examiner can normally be reached on M-F (7:15 AM - 3:45 PM).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John L. Goff/
Primary Examiner, Art Unit 1791